REMARKS

Upon entry of this reply, claims 1, 4-21 and 24-29 will remain pending.

Reconsideration and allowance of the application are respectfully requested.

Priority

Applicant once again acknowledges the Examiner's indication regarding the parent PCT application, and reminds the Examiner that PCT/EP03/13873 entered the U.S. national stage and was awarded Application No. 10/582,223, and published as US 2007/0081950 A1. The Examiner is once again requested to review the file wrapper of this parent application at the Patent and Trademark Office, including the Office Actions mailed therein. If the Examiner needs any documents, the Examiner is requested to contact the undersigned.

Restriction Requirement

Applicant is permitting non-elected claims 16-21 to remain pending subject to rejoinder upon allowance of the elected subject matter.

Response To Art Based Rejections

The following art based rejections are set forth in the Office Action:

(a) Claims 1, 4, 6, 8 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said (translation, WO 97/19668) in view of Georgiades, US 2002/0061282.

(b) Claims 5, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said (translation, WO 97/19668) in view of Georgiades, US 2002/0061282, and further in view of Holme et al. (hereinafter "Holmes"), U.S. Patent No. 6,685,916.

(c) Claims 7, 9, 24 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said (translation, WO 97/19668) in view of Georgiades, US 2002/0061282, and further in view of Witt et al. (hereinafter "Witt"), U.S. Patent No. 6,350,438.

(d) Claims 11, 14 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said (translation, WO 97/19668) in view of Georgiades, US 2002/0061282, and further in view of Majeti et al. (hereinafter ("Majeti"), U.S. Patent No. 6,682,722.

Reponses to Rejections set forth in paragraphs (a), (b), (c) and (d)

In response to these grounds of rejection, Applicant submits that Tame-Said in view of Georgiades does not teach or suggest the subject matter recited in Applicant's claims for at least the reasons set forth herein, and none of the documents used in the rejections of record, whether taken alone or in any combination, overcomes the deficiencies of any combination of Tame-Said and Georgiades.

The examiner is reminded that according to Applicant's invention calcium pyrophosphate has been surprisingly found to exhibit improved stain removal when incorporated into a lozenge comprising a water-soluble lozenge base. **Applicant has found that the tooth-whitening effectiveness of calcium pyrophosphate is not limited to mechanically applied (e.g., by brushing action) oral compositions such as dental creams, <u>but is seen to a surprisingly high degree in a lozenge composition that dissolves in the oral cavity owing to the water-soluble lozenge base</u>. Significantly, this effect is seen at a surprisingly low concentration of calcium pyrophosphate being between 1 .5 % and 4.0 % by weight of the composition.**

Applicant's independent claim 1 is directed to a solid oral tooth whitening lozenge composition comprising more than 75% by weight of solid materials, said composition

comprising:

a) a water-soluble lozenge base,

b) lozenge additives, and

c) a tooth whitening agent comprising calcium pyrophosphate, said calcium pyrophosphate is present in an amount **of between 1.5 % and 4.0 % by weight** of the composition.

In contrast, Tame-Said discloses a toothpaste and mouthwash composition in tablet form which dissolves in the mouth. The object of the composition of Tame-Said is the prevention of periodontal disease or caries (abstract; page 1, lines 8-13).

Tame-Said teaches that each tablet comprises ascorbic acid, sodium bicarbonate, tricalcium phosphate, sodium lauryl sulfate, arabic gum, natural sweeteners and flavouring agents. Tame-Said is silent on the use of calcium pyrophosphate in the composition. Tame-Said teaches a considerably higher weight percentage of polishing agent, i.e., 11.59% of tricalcium phosphate (40mg. of tricalcium phosphate to 345 total mg.) then recited in Applicant's independent claim 1. **Thus, Applicant's independent claim 1 is distinguished from Tame-Said by at least the amount of calcium pyrophosphate being between 1.5 % and 4.0 % by weight of the composition.**

Georgiades relates to a tooth-whitening composition comprising a whitening agent selected from the group consisting of dicarboxylic acids and salts of dicarboxylic acids, and the essential oils thymol, methyl salicylate, menthol, and eucalyptol. The composition of Georgiades can be provided in a variety of forms including dental cream, toothpaste, toothpowder, lozenges, films, micro-capsule, compressed tablet, pastille, nougat or chewing gum [0037]. In addition, a long list of possible polishing materials is given, including calcium pyrophosphate [0037]. Georgiades also teaches that such polishing materials are generally present in a nearly all-

embracing range of about 1 - 99 wt%, whereas the actual working range is about 20 - 75 wt% and about 70 - 99 wt% for toothpaste and toothpowder, respectively. Georgiades is devoid of any working ranges or examples relating to a lozenge.

A review of Georgiades reveals that the disclosure used in the rejection is basically set forth in paragraph [0037]. From this paragraph, it would appear that even if one having ordinary skill in the art would have replaced the tricalcium phosphate of Tame-Said with calcium pyrophosphate, higher concentrations of calcium pyrophosphate would be employed as compared to that recited in Applicant's claims. In this regard, Tame-Said discloses 11.59% of tricalcium phosphate and one having ordinary skill in the art reading Georgiades would understand that Georgiades prefers even higher concentrations. Accordingly, one having ordinary skill in the art would not have manipulated amounts in the manner asserted in the rejection to arrive at Applicant's recited calcium pyrophosphate being present in an amount of between 1.5 % and 4.0 % by weight of the composition. The only teaching or suggestion to arrive at such a range of calcium pyrophosphate is within Applicant's disclosure, and the use of Applicant's disclosure in a rejection is improper.

Toothpaste as well as toothpowder are oral hygiene products that are applied to the teeth by physical action, i.e., by brushing motion. In contrast, a lozenge simply dissolves in the mouth. Consequently, one having ordinary skill in the art seeking to improve the tooth whitening effect of the tablet of Tame-Said **would certainly look to increase the amount of abrasive material as compared to the value given in Tame-Said** (> 11 wt%) **or the range given for toothpaste in Georgiades** (>20 wt%). There is neither an incentive nor a reasonable expectation of success following the prior art of record for one having ordinary skill in the art to decrease the amount of abrasive material in Tame-Said to the range of 1.5 - 4 wt% recited in Applicant's

claims. The tooth whitening effect of Applicant's recited lozenge is highly counter-intuitive and surprising from any disclosure of Tame-Said or Georgiades let alone any combination thereof if for the sake of argument their disclosures are combinable.

This is even more so as the prior art considers calcium pyrophosphate as an abrasive material with a particularly low polishing effect as compared to, for example, calcium carbonate (see, for example, Applicant's application as filed at page 2, lines 17-18). One having ordinary skill in the art seeking to provide a tooth whitening lozenge would thus be directed to even higher amounts of calcium pyrophosphate than what is disclosed in any of the cited art. Thus, even if for the sake of argument calcium pyrophosphate is chosen from the list of materials disclosed in Georgiades, both the selection of calcium pyrophosphate from the material list as well as the selection of a lozenge from the dentifrice list of Georgiades would point one having ordinary skill in the art to a higher concentration of polishing material as compared to the value given in Tame-Said (> 11 wt%).

As discussed in Applicant's originally filed application, the use of abrasive materials such as calcium pyrophosphate in confectionary such as lozenges would not be expected to cause a tooth whitening effect comparable to the effect when used in compositions intended for continuous chewing or similar physical application (Applicant's application at page 3, line 31 to page 4, line 6). This is a rather intuitive prejudice of the prior art since lozenges are not chewed or applied physically to the same extent as chewing gum or toothpaste. As a consequence the stain removal effect of the abrasive material would be expected to be insignificant due to the negligible mechanical rubbing on the tooth surface.

According to the present invention, it has however been surprisingly found that calcium pyrophosphate in an unexpectedly low amount of between 1.5 % and 4.0 % by weight of a

lozenge composition comprising more than 75% by weight of solid material has a particularly efficient stain removal effect.

This is even more surprising since the effect is significantly increased as compared to calcium carbonate, which has been considered to be a more efficient abrasive material in the prior art. As an example, a lozenge composition comprising 2.08 % by weight of calcium pyrophosphate is approximately 7 times more efficient than comparable prior art compositions (see Applicant's Table 1). This surprising effect is certainly non-obvious and in no way taught or suggested by the cited prior art.

The rejection makes reference to MPEP 2144.05 saying that a *prima facie* case of obviousness exists for a claimed range lying in a broader prior art range. While this general statement may be appropriate depending upon circumstances, the Examiner is respectfully pointed to the concrete situation at hand. The prior art, Georgiades, makes mention of an excessively broad range of 1 – 99 wt% of abrasive material, thus attempting to embrace all possible embodiments. Such range is certainly not a technical teaching as such but rather a means of covering a territory as broad as possible. In MPEP 2144.05, reference is made to this very situation in that "if the reference's disclosed range is so broad as to encompass a very large number of possible distinct compositions, this might present a situation analogous to the obviousness of a species when the prior art broadly discloses a genus". This is clearly the case here. Not only is the weight percentage disclosed as an excessively broad range, but also the abrasive material (calcium pyrophosphate) has to be selected from a list of considerable length (see [0037] of Georgiades**). It is respectfully submitted that the combined selection of calcium pyrophosphate at the claimed weight percentage is clearly non-obvious in view of either Georgiades or Tame-Said as well as their combination. Both pieces of prior art teach**

away from a range of 1.5 -4 wt% calcium pyrophosphate for the reasons set forth above. In such a situation, the prima facie finding of obviousness can, with all due respect, no longer be maintained (see MPEP quoting In re Geisler).

Holme, Witt and Majeti do not overcome the deficiencies of Tame-Said and/or Georgiades for at least the reasons set forth above. Moreover, Holme, Witt and Majeti do not disclose the combination of features recited in the claims under rejection.

For example, Majeti is used in the rejection for its disclosure of urea peroxide as a bleaching agent. However, the dependent claims each recite the presence of urea which is disclosed in Appellant's specification, at page 7, lines 14 and 15, as a plaque acid buffer. In contrast, the rejection contends that Majeti discloses urea peroxide as a bleaching agent. There is no teaching or suggestion in the documents used in the rejection of the inclusion of urea in a solid oral tooth whitening lozenge composition comprising more than 75% by weight of solid materials as recited in Applicant's claims. In this regard, the rejection contends that it is immaterial what the advantage is. However, the rejection still does not establish that the use of urea would have been obvious as the only assertion of obviousness relates to urea peroxide, not urea. Accordingly, the rejection is without sufficient basis in relying upon a bleaching agent of urea peroxide in the prior art, and does not establish the obviousness of Applicant's recited subject matter including urea let alone urea in the concentrations recited in Applicant's claims.

Still further, Applicant submits that any combination of the cited documents would not arrive at the subject matter recited in each of Applicant's dependent claims at least for the reasons set forth above, and for the additional features recited in each dependent claim in combination with the subject matter from their parent claims.

Thus, for at least the reasons set forth above, the rejections are without appropriate basis and should be withdrawn.

CONCLUSION

Entry and consideration of the present amendment, reconsideration of the Office Action, and allowance of the present application and all of the claims therein are respectfully requested and believed to be appropriate.

Should the Examiner have any questions or comments regarding this response, or the present application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
Edith SORENSEN

/Arnold Turk/
Reg. No. 33,094
Arnold Turk

Neil F. Greenblum
Reg. No. 28,394

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GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191